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09/599,987	06/23/2000	Richard E. Fulton	3663-5	9195

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EXAMINER

WEBB, JAMISUE A

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/599,987

Applicant(s)

FULTON, RICHARD E. *MT*

Examiner

Jamisia A. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16, 17 and 19-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 16, 17, 19, 31-40 and 43-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-30, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Drawings***

1. Upon further review of the case and the formal drawings submitted previously, the proposed drawings that were filed as formal drawings filed on 11/19/01 that were previously approved, are now disapproved because the drawings contain corrections (new reference numbers) and the corrections are not presented in the form of a pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted. See MPEP § 608.02(v).
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not contain reference sign(s) mentioned in the description. A proposed drawing correction or corrected drawings are required in reply to the Office action. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include reference sign(s) not mentioned in the description. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action. The objection to the drawings will not be held in abeyance.
4. It should be noted that when adding figure numbers to both the drawings and to the specification, applicant should take careful notice not to add any new matter, and it should be clear the items being labeled are completely described in the specification.

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*Amendment*

5. It should be noted that the applicant has amended claims 1-3, 1-14 and 16, which are drawn to a non-elected invention and are withdrawn from consideration. These claims are still withdrawn from consideration and this application contains claims 1-14, 16, 17, 19, 31-40, and 43-55 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. The amendment filed 12/18/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the applicant has added in Claim 20 the limitation of "means for providing mechanical motion causing said catheter to rotate", Claim 26 states "mechanical motion generates vibrations effective to disrupt a clot", where as both of these limitations are present in the specification, there is not an embodiment that encompasses both limitations. There is not one embodiment where the means for providing mechanical motion is both rotating and causing vibrations. Claim 41 also discloses that an intermittent mechanical motions of the catheter is caused by the delivery of a lytic agent in pulses, there is also not one embodiment in the specification where motion is caused by rotation of the catheter and delivery of a lytic agent. These are all separate embodiments and the combination of the embodiments added to the claims constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

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***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 26, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See above for reasons of new matter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. Claims 41 and 42 recite the limitation "said pump". There is insufficient antecedent basis for this limitation in the claims.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. Claims 20-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Auth (4,445,509).

14. With respect to Claims 20 and 26: Auth discloses a pharmomechanical device with a means for increasing the surface area of a clot (1), and a means for providing mechanical motion to a catheter (4). Auth discloses the catheter to be a corkscrew configuration (See Figures 5-7), which rotates once inserted within patient and that breaks up a clot but does not cut or damage the blood vessels (column 6, lines 37-39, column 7, lines 11-13).

15. With respect to Claim 21-23: It is the examiner's position that the device is perfectly capable of running for a prolonged period of time, if the motor is turned on for 24 hours, then the catheter will run for 24 hours.

16. With respect to Claims 24-25: The applicant has not provided any additional structure to cause the mechanical means to have intermittent operation, therefore it is the examiner's position the motor (4) is capable of being turned on and off for a prolonged period of time and for equal amounts of time.

17. With respect to Claims 27, 29 and 30: Auth discloses the motor being connected to the top which rotates over a length, the examiner considers this a substantial length, due to the fact that wire connecting the tip (1) has a substantial length (See Figure 1 and 2).

18. With respect to Claim 28: Reference numeral 24 can be used to eject chemicals used for injecting chemicals which dissolve emboli (column 7, lines 60-63). As seen in Figure 7, tip 7, can be used as an occluding device which would hold the fluid coming out of tip 23 in place.

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***Response to Arguments***

19. Applicant's arguments with respect to claim 20-30, 41 and 42 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamisue A. Webb whose telephone number is (703) 308-8579. The examiner can normally be reached on M-F (7:30 - 4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703)308-1957. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jaw

March 6, 2003

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